| P | | |
|--|--|------------------------------|
| Notice of Allowability | Application No. | Applicant(s) |
| | 10/075,097 | EKWURIBE ET AL. |
| | Examiner | Art Unit |
| | Andrew D. Kosar | 1654 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. | | |
| 1. This communication is responsive to <u>9/6/05</u> . | | |
| 2. X The allowed claim(s) is/are 114-169 and 208-213. | | |
| 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some* c) None of the: 1. Certified copies of the priority documents have been received. | | |
| 2. Certified copies of the priority documents have been received in Application No | | |
| 3. Copies of the certified copies of the priority documents have been received in this national stage application from the | | |
| International Bureau (PCT Rule 17.2(a)). | | |
| * Certified copies not received: | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. | | |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. | | |
| (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached | | |
| 1) hereto or 2) to Paper No./Mail Date | | |
| (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date | | |
| Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). | | |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. | | |
| Attachment(s) | | |
| 1. ☑ Notice of References Cited (PTO-892) | 5. Notice of Informal P | atent Application (PTO-152) |
| 2. Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. Interview Summary | (PTO-413), |
| 3. Information Disclosure Statements (PTO-1449 or PTO/SB/0 | Paper No./Mail Da 18), 7. ☐ Examiner's Amendr | te nent/Comment |
| Paper No./Mail Date 4. | 8. 🛛 Examiner's Stateme | ent of Reasons for Allowance |
| of Biological Material | 9. | · |
| • | - | |
| | | |

Application/Control Number: 10/075,097

Art Unit: 1654

REASONS FOR ALLOWANCE

Response to Amendment/Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's after-final amendments to the claims and specification, filed September 9, 2005 have been entered.

All rejections and/or objections not specifically addressed are herein withdrawn.

Applicant's amendments to the claims and arguments therein, filed September 9, 2005 have been considered and are persuasive.

The rejections of claims 114-122, 126, 127, 129-150, 154, 155, 157-169, and 208-213 under 35 USC § 102(a), claims 114-122, 126, 127, 129-150, 154, 155, 157-169, and 208-213 under 35 USC § 102(b), claims 114-127, 129-169, and 208-213 under 35 USC § 103(a), and claims 114-169 and 208-213 under 35 USC § 103(a) are withdrawn.

Claims 114-169 and 208-213 are allowed.

The following is an examiner's statement of reasons for allowance: Upon entry of the amendment, the prior art does not teach or suggest the instant method of administering oral insulin to a human patient. The closest prior art of record, Allaudeen, teaches administration of oral insulin to dogs, but not to humans at the instant dosages and schedule. Additionally, US Patents 5,653,987 and 4,898,733 teach oral insulin in a PEG coated capsule, but do not teach conjugates of PEG-insulin in oral administration.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Page 3

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.

Art Unit 1654

BRUCE R. CAMPELL, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Brue Campell